

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/744,574	ELGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Notice of Appeal filed on 5/24/05 and Appeal Brief filed on 8/24/05.
2.  The allowed claim(s) is/are 9, 11 and 13-25.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

**EXAMINER'S AMENDMENT**

Claims 9, 11 and 13-25 are pending in the application as of the Appeal Brief and Amendment received on August 24, 2005.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Csaba Henter on November 30, 2005.

The application is being amended as follows:

In claim 23, after "ciproterone acetate," please delete ",".

On page 1 of the specification, after the title "Use of Biogenic Estrogen Sulfamates for Hormone Replacement Therapy" and before the first full paragraph, please insert:

"Cross-Reference to Related Applications

This application is a 371 of PCT/DE99/01496, filed May 13, 1999."

The following is an examiner's statement of reasons for allowance:

The prior art does not teach or suggest the intermittent administration of an estrogen sulfamate in the dosages as claimed to achieve hormone replacement therapy. The closest prior art can be found in the teachings of WO 96/05216 to Siemann and U.S. Patent No. 5,314,694 to Gale et al. However, in a decision mailed March 25, 2004, the Board of Patent Appeals and Interferences determined that the daily estrogen administrations as taught by the Siemann and Gale references did not render obvious the instantly claimed method of intermittent administration (i.e., less often than daily.)

In this same decision, the Board affirmed a provisional rejection of the claims for obviousness-type double patenting over U.S. Patent No. 6,653,298 to Potter et al, because Applicants failed at the time to dispute the merits of the rejection. However, Applicant's current arguments regarding the rejection of claims 9, 11 and 13-17 for obviousness-type double patenting over claims 2, 4-7 and 11-18 of U.S. Patent No. 6,653,298 to Potter et al. have been considered and found persuasive. The claims in the 6,653,298 patent do not teach or suggest an *intermittent* administration of estrogen sulfamate, and instead claim dosages of, for example, no greater than 200 $\mu$ g *per day*

(see claim 2, for example.) Accordingly, as the claims of the 6,653,298 patent do not teach or provide any motivation for the instantly claimed *intermittent* administration, the obviousness-type double patenting rejection has been withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER